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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,457	12/07/2001	Anthony Cerami	10162-006-999	5299

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EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/017,457	CERAMI ET AL.	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-31 are drawn to an immune modulation device, classified in class 436, subclass 518.

II. Claims 32-40 are drawn to a method of modulating an immune system, classified in class 435, subclass 4.

III. Claims 41 and 42 are drawn to a method of obtaining cells, classified in class 435, subclass 7.1.

IV. Claims 43-49 are drawn to a method of manufacturing an immune modulation device, classified in class 435, subclass 284.1.

V. Claims 50-52 are drawn to an immune modulation device comprising pores formed by laser ablation, classified in class 436, subclass 519.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of a) each of groups I and V and b) each of groups II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of groups I and V can be used in a materially different process of filtration or separation of analyte from a sample.

3. Inventions of a) each of groups I and V and b) group IV are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case the products of groups I and V can be made by a materially different process of incorporating a quantity of antigen inside a fibrous scaffolding before placing the scaffolding within an interior lumen of an impermeable biocompatible shell.

4. Inventions of group I and group V are patentably distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The product of group I requires an impermeable biocompatible shell, which is not required of the product of group V. The product of group V requires pores formed by laser ablation, which is not required of the product of group I.

5. Inventions of a) each of groups II and III and b) group IV are patentably distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The methods of groups II and III are drawn to a method of using an immune modulation device, while the method of group IV is drawn to a method of manufacturing an immune modulation device.

6. Inventions of group II and group III are patentably distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The method of group II requires modulating an immune system in an animal to an antigen, which is not required of the method of groups III. The method of group III requires obtaining immune cells from an animal, which is not required of the method of group II.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. §821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. § 804.01.

9. This application contains claims directed to the following patentably distinct species of the claimed invention: Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic. If group I is elected, ONE species from *each* of the species groups A and C must also be elected. Furthermore, if species group A is elected, ONE species from species group B must also be elected.

Group A is drawn to a bioabsorbable immune devices is made from a polymer material selected from: aliphatic polyesters, poly(amino acids), copoly(ether-esters), polyalkylenes

oxalates, polyamides, tyrosine derived polycarbonates, poly(iminocarbonates), polyorthoesters, polyoxaesters, polynmidoesters, polyoxaesters containing amine groups, poly(arlhydrides), polyphosphazenes and biomolecules.

Group B is drawn to the aliphatic polyester selected from: homopolymers and copolymers of lactide (which includes lactic acid, D-, L- and meso lactide), glycolide (including glycolic acid), ε- caprolactone, p-dioxanone (l,4-dioxan-z-one), trimethylene carbonate (1,4-dioxan-z-one), alkyl derivatives of trimethylene carbonate, delta-valerolactone, beta-butyrolactone, gamma- butyrolactone, ε-decalactone, hydroxybutyrate, hydroxyvalerate, l,4-dioxepan-z-one (including its dimer 1,5,8,12-tetraoxacyclotetradecane-7,l4-dione), 1,5-dioxepan-z-one, 6,6-dimethyl-1,4-dioxr-2,5-dione, 2,5-diketomorpholine, pivalolactone, gamma, gamma- diethylpropiolactone, ethylene carbonate, ethylene oxalate, 3-methyl-l ,4-dioxane-2,5- dione, 3,3-diethyl-1,4-dioxan-2,5-dione and 6,8-dioxabicycloctane-7-one.

Group C is drawn to the shell material selected from: homopolymers and copolymers of lactide (which includes lactic acid, D-, L- and meso lactide), glycolide including glycolic acid), ε-caprolactone, p-dioxanone (1,4-dioxan-2-one), trimethylene carbonate (1,3-dioxan-2-one), alkyl derivatives of trimethylene carbonate, 1,4-dioxepan-2-one (including its dimer 1,5,8,12-tetraoxacyclotetradecane-7,14-dione), 1,5-dioxepan-2-one, 6,6-dimethyl-1,4-dioxan-2-one, poly(p-dioxanone), glycolide-co-ε-caprolactone, glycolide-co-trimethylene carbonate, glycolide-co-1,5-dioxepan-2-one, and 6,6-dimethyl-1,4-dioxan-2-one.

Group D is drawn to a biocompatible fibrous scaffolding material selected from: homopolymers and copolymers of lactide (which includes lactic acid, D-, L- and meso lactide), glycolide (including glycolic acid), ε-caprolactone, p-dioxanone (1,4-dioxan-2-one), trimethylene carbonate (1,3-dioxan-2-one), alkyl derivatives of trimethylene carbonate, 1,4-dioxepan-2-one (including its dimer 1,5,8,12-tetraoxacyclotetradecane-7,14-dione), 1,5-dioxepan-2-one, 6,6-dimethyl-1,4-dioxan-2-one, polyglycolide, poly(p-dioxanone), glycolide-co-.epsilon.-caprolactone, glycolide-co-trimethylene carbonate and glycolide-co-lactide.

Group E is drawn to a natural antigen selected from: Actinobacillus equuli, Actinobacillus lignieresi, Actinobaccilus seminis, Aerobacter aerogenes, Borrelia burgdorferi, Babesia microti, Klebsiella pneumoniae, Bacillus cereus, Bordetella pertussis, Brucella abortus, Brucella melitensis, Brucella ovis, Brucella suis, Brucella canis, Campylobacter fetus, Campylobacter fetus intestinalis, Chlamydia psittaci, Chlamydia trachomatis, Clostridium tetani, Corynebacterium acne Types 1 and 2, Corynebacterium diphtheriae, Corynebacterium equi, Corynebacterium pyogenes, Corynebacterium renale, Coxiella burnetii, Diplococcus pneumoniae, Escherichia coli, Ehrlichia phagocytophila, Ehrlichia equi, Fusobacterium necrophorum, Granuloma inguinale, Haemophilus influenzae, Haemophilus vaginalis, Group b Hemophilus ducreyi, Lymphopathia venereum, Leptospira pomona, Listeria monocytogenes,

Microplasma hominis, Moraxella bovis, Mycobacterium tuberculosis, Mycobacterium laprae, Mycoplasma bovigenitalium, Neisseria gonorrhea, Neisseria meningitidis, Pseudomonas maltophiia, Pasteurella multocida, Pasteurella ham emolytica, Proteus vulgaris, Pseudomonas aeruginosa, Rickettsia prowazekii, Rickettsia mooseri, Rickettsia rickettsii, Rickettsia tsutsugamushi, Rickettsia akari, Salmonella abortus ovis, Salmonella abortus equi, Salmonella dublin, Salmonella enteritidis, Salmonella heidleberg, Salmonella paratyphi, Salmonella typhimurium, Shigella dysenteriae, Staphylococcus aureus, Streptococcus ecoli, Staphylococcus epidermidis, Streptococcus pyrogenes, Streptococcus mutans, Streptococcus Group B, Streptococcus bovis, Streptococcus dysgalactiae, Streptococcus equisimili, Streptococcus uberis, Streptococcus viridans, Treponema pallidum, Vibrio cholerae, Yersina pesti, Yersinia enterocolitica, Aspergillusfumigatus, Blastomyces dermatitidis, Candida albicans Crytococcus neoformans, Coccidioides immitis, Histoplasma capsulatum, influenza viruses, HIV, human papilloma virus, cytomegalovirus, polio virus, rabies virus, Equine herpes virus, Equine arteritis virus, IBR--IBP virus, BVD--MD virus, Herpes virus (humonis types 1 and 2), Schistosoma, Plasmodium, Onchocerca, and parasitic amoebas.

Each of the polymers of groups A-D are patentably distinct because they have different chemical structures. Each of the antigens of group E are patentably distinct because they have different biological functions and structures.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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03/17/05